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EXAMINER

PAK, YONG D

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1652

DATE MAILED: 12/05/2001

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/501,730

Applicant(s)

SHERMAN ET AL.

Examiner

Yong Pak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 11-16 and 29-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 17-28 and 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) g.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

The amendment filed on October 9, 2001, amending claims 8-10, has been entered.

Claims 1-33 are pending.

Election/Restrictions

Claims 11-16 and 29-32 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 6.

Claim Rejections - 35 USC § 102

Claims 1-8, 17-28 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by R&D Focus Drug News.

R&D Focus Drug News teaches a pegylated recombinant uricase. The specification teaches that the unfractionated PKS of SEQ ID NO:3 of the instant invention was obtained from Bio-Technology General Limited (page 16, line 21). Because the referenced uricase is used as a therapeutic composition in humans, one skilled in the art would recognize that said uricase is free of large aggregates. Comparison of the instant products with prior art is difficult since the Office is not equipped to manufacture the claimed product and /or prior art products that appear to be related and conduct comparisons. The burden is on the applicant to establish a patentable distinction between the claimed and referenced uricase. Regarding claim 33,

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patentability of a product does not depend on the method used in producing the product (MPEP 2113). Therefore, the R&D Focus Drug News reference anticipates claims 1-8, 17-28 and 33.

Claims 1-8, 17-28 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by PuricaseTM Registration No. 2,246,623.

PuricaseTM (Registration No. 2,246,623) teaches a PEG-uricase. Because the referenced uricase is used as a pharmaceutical composition in humans, one skilled in the art would recognize that said uricase is free of large aggregates. Comparison of the instant products with prior art is difficult since the Office is not equipped to manufacture the claimed product and /or prior art products that appear to be related and conduct comparisons. The burden is on the applicant to establish a patentable distinction between the claimed and referenced uricase. Regarding claim 33, patentability of a product does not depend on the method used in producing the product (MPEP 2113). Therefore, PuricaseTM (Registration No. 2,246,623) anticipates claims 1-8, 17-28 and 33.

Claim Rejections - 35 USC § 103

Claims 1, 4 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over PuricaseTM (Registration No. 2,246,623) in view of Wu et al.

PuricaseTM (Registration No. 2,246,623) teaches a uricase, as discussed above.

The difference between the reference and the instant application is that PuricaseTM (Registration No. 2,246,623) does not teach a uricase in which His at position 97 has replaced Tyr.

Wu et al. teach that baboon, porcine and mouse uricases are highly conserved (page 9413, 2nd column and Fig 2 -b). Mouse and porcine uricase has a His at position 97, while baboon has a Tyr at position 97. Histidines play a role in the copper binding sites of a uricase (page 9413-9414). A portion can be construed as one or more amino acids.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to make a uricase by replacing Tyr 97 of the baboon uricase with Try97 of the porcine uricase. One would be motivated to replace a residue with a conserved residue because conserved amino acids very often impart the characteristic property of an enzyme and because histidines play a role in binding copper and uricase is a copper binding enzyme. One of ordinary skill in the art would have had a reasonable expectation of success since site specific mutations are routinely performed in the art.

Claims 1, 4 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over PuricaseTM (Registration No. 2,246,623) in view of Wu et al.

PuricaseTM (Registration No. 2,246,623) teaches a uricase, as discussed above.

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The difference between the reference and the instant application is that PuricaseTM (Registration No. 2,246,623) does not teach a uricase truncated at one or both termini.

Wu et al. teach that porcine urate oxidase is six amino acid residues shorter than that of rat uricase (page 9414, 2nd column) but the two uricases are highly conserved throughout the coding region (page 9413, 4th paragraph).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to make a functional uricase of a smaller size by deleting residues from both N -terminus. The motivation is to determine whether residues at the N-terminus are important for uricase activity and to use a smaller functional fragment of uricase in view of convenience. One of ordinary skill in the art would have had a reasonable expectation of success since site specific mutations are routinely performed in the art.

Rejections and/or objections not reiterated from previous Office action are hereby withdrawn.

The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

Applicant's arguments filed October 9, 2001 have been fully considered but they are not persuasive.

The declaration filed on October 9, 2001 under 37 CFR 1.131 is sufficient to overcome the Caliceti et al. *Bioconjugate Chem.* 1999, 10, 638-646 reference.

Claim Objections

Claim 10 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Applicants argue that claim 1 refers to a uricase molecule that may be full-length or may be truncated and that Claim 10 limits the scope of claim 1 by encompassing only the truncated molecules. The examiner disagrees.

Claim 1 is drawn to only full-length enzymes and not fragments. Also, claim 10 is not drawn to only truncated molecules because claim 10 is drawn to uricases comprising a truncated amino and/or carboxyl terminus.

Claim Rejections - 35 USC § 112

Claims 5, 9, and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 5 and 9, applicants argue that uricases having substantially the sequence of a porcine, bovine, ovine, or baboon liver uricase are any mutations in the sequence that are not insubstantial, mutations not imparting an activity of less than 75% of wild type protein. The examiner disagrees. The metes and bounds of the claim are still unclear because various polypeptides can be "substantially" the sequence of a porcine, bovine, ovine, or baboon liver uricase and many polypeptides can contain a portion of porcine and baboon liver uricases.

Regarding claim 10, applicants argue that "...comprises an amino terminal and a carboxy terminus" is not redundant because the recitation of the termini affords proper antecedent basis for the latter half of the claim. The examiner disagrees. Any amino acid sequence comprises of an amino and carboxyl terminus. The claim as written is also confusing because the claim is drawn to uricase having an amino or carboxyl terminus but wherein one or two of the terminus is truncated.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4534.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong Pak
Patent Examiner

November 30, 2001



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